(g) A software with a capability of dividing the image into three Zones at 20 minute intervals, using the ZONE icon;

(h) A software with a capability of inverting the selected image using the INVERT icon;

(i) A software with a capability of switching over to Notepad, Word pad and MS Word, using the EDITOR Icon;

(j) A software with a capability of operational information about various features of the Software using, the HELP icon; and

(k) Software with a capability of saving the data generated using the SAVE AS icon as JPEG file format.

48. Use of fingerprints of contour and 3 –D chromatograms of the constituents as claimed in any of the preceding claims are the basis for identification of chemical constituents.

REMARKS

The present Preliminary Amendment includes several changes to the pending claims and the cancellation of Claims 11, 18, and 23. Applicants respectfully submit that no new matter has been added by these changes.

MARKED-UP CHANGES

Attached hereto is a marked-up version of the changes made to the

claims by the current amendment. The attached paper is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

CONCLUSION

In light of the above amendments and remarks, Applicants respectfully submit that all pending claims as currently presented are in condition for allowance. If, for any reason, the Examiner disagrees, please call the undersigned attorney at 202-624-3947 in an effort to resolve any matter still outstanding *before* issuing another action. The undersigned attorney is confident that any issue which might remain can readily be worked out by telephone.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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Dated: **June 28, 2003**

VERSION WITH MARKINGS TO SHOW CHANGES MADE
(USSN 09/779,377)

IN THE CLAIMS:

Claims 11, 18, and 23 have been cancelled.

Claims 1 through 10, 19 through 22, and 24 through 48 have been amended as follows:

1. A method for detection and identification of [principles from] constituents of extracts [of] from plants or [animal] animals, natural or synthetic sources possessing medicinal value, using chromatographic finger printing techniques, [said] the method comprising the steps of:

[i)] i. extracting [the] organic or organo-metallic [molecules] compounds from plants or animal, natural or synthetic sources using a suitable solvent;

[ii)] ii. subjecting the extract obtained in step [(i)] i. to [the] separation [analysis] based on pH and polarity, using High Pressure Liquid Chromatography (HPLC) techniques;

iii. generating contour and 3D chromatograms of the [ingredients] constituents eluted [based on the pH and polarity] in step ii.;

iv. converting the 3-D and contour chromatogram obtained into a colored image, analyzing the colored image for its individual colors using the co-ordinates denoting all its 3-dimensional properties of [the] said image by using [an inbuilt] a newly-developed in-built software;

v. denoting the concentrations of the various constituents eluted with time;

vi. generating a chromatogram based on color analyzed, having peaks at various retention times along with conjugative properties of the [molecules] constituents;

vii. identifying the compounds in [the] said ingredients by the [UV-Vis] Ultra Violet and Visible electromagnetic radiation absorptive properties of the various constituents in the image;

viii. identifying, determining and classifying the compounds eluted as polar, medium polar and less or non-polar based on the polarity and conjugative properties;

ix. generating a barcode for a selected peak using the X-axis [X axis] as Retention Time, the Y-axis [Y axis] as Wavelength, R as number of Red Pixels, G as number of Green Pixels and B as number of Blue Pixels; and

x. generating a database of fingerprints and barcodes and identifying the respective compounds [in the samples] of the extract.

2. A method as claimed in claim 1, wherein [wherein,] the solvents with different polarities are [selected] used for extraction based on the hydrophilic and hydrophobic nature of the constituents present in the sample under study, and ethyl alcohol is used as a solvent for preparation and for standardization of [medicines] medicinal extracts.

3. A method as claimed in claim 1, wherein [wherein,] the fingerprints are developed for the same [medicine extracted] medicinal extract under different pH ranges.

4. A method as claimed in claim 1, wherein [wherein,] the HPLC technique used is by employing [apparatus used is selected from] any commercially available HPLC apparatus with the Photo Diode Array detector, preferably with a gradient or ternary system of pumps.

5. A method as claimed in claim 1, wherein the method is carried out using standard analytical parameters like extraction with ethyl alcohol, maintaining a run time of 0-60 minutes, eluting with a mobile phase of acetonitrile along with a phosphate buffer having a pH in the range of 5.5-7.5, and an Ultra Violet and Visible detector having the electromagnetic radiation range of 200-800nm for fingerprinting, chemical and therapeutic standardization [wherein, the pH and polarity of the mobile phase is controlled by varying the ratio of the mixture 0 to 100% of an aqueous solvent, water or a buffer at a required pH by using a salt (like Potassium Di-Hydrogen orthophosphate or Di potassium hydrogen orthophosphate and phosphoric acid maintaining the required pH) with a non-aqueous solvent].

6. A method as claimed in claim 1, wherein the solvent used in step iii. is selected from a group consisting of [wherein,] the non-aqueous, organic and aqueous, water or buffer at a known pH [are the solvents used in step 1(iii) and] are selected based on the range of polarity.

7. A method as claimed in claim 1, wherein [wherein,] converting the contour chromatograms into a colored image [comprising the] consisting of conjugative and polarity properties of the constituents of the [medicine] medicinal extract under study.

8. A method as claimed in claim 1, wherein [wherein,] the therapeutic efficacy of a [medicine] medicinal extract (single or formulated) is assessed using the quality of the constituents present in a particular polarity and UV-Vis absorptive zone.

9. A method as claimed in claim 1, wherein [wherein,] the software generates a barcode for a selected peak or peaks or image using the [X axis] X-axis as Retention Time, [Y axis] the Y-axis as Wavelength, R as number of Red Pixels, G as number of Green Pixels and B as number of Blue Pixels as the coordinates, provided by the software, which makes the product propriety for an industry.

10. [A method as claimed in claim 1 wherein, the software used is called Rainbow having] A software called "Rainbow" for detection and identification of extracts of plant or animal origin, natural or synthetic sources possessing medicinal values obtained as claimed in cliam 1 with the following features:

(a) a software [with a facility] capable of opening chromatographic fingerprint images in different Formats (extensions) like BMP, JPEG, TIF, GIF from the file folders and analyze it for different colors present in the image with single pixel sensitivity;

(b) a software [with a facility of display] capable of creating a display of the pixel information in the form of 1.a graph having a scale of X (0-(min. time scale) and Y (200-800nm) coordinates and 2. a Pie diagram with individual values of each peak (Automatic and Manual) in two separate columns beside the graph;

(c) a software [with a facility] capable of printing all the data generated after analysis using the PRINT Icon;

(d) a software [with a facility] capable of changing the page setup for printing using the PAGE SETUP Icon;

(e) a software [with a facility] capable of selecting a part of the image and [analyze] making an analysis using the RESIZE Icon;

(f) a software [with a facility] capable of opening any number of image analysis windows for different images, and [display] of displaying the status in the WINDOW icon;

(g) a software [with a facility] capable of dividing the image [in to] into three Zones at 20 [min interval] minute intervals, using the ZONE icon;

(h) a software [with a facility] capable of inverting the selected image using the INVERT icon;

(i) a software [with a facility] capable of switching over to Notepad, Word pad and MS Word, using the EDITOR icon;

(j) a software [with a facility of] capable of providing operational information about various features of the Software using[,] the HELP icon; and

(k) software [with a facility] capable of saving the data generated using SAVE AS icon as JPEG file format.

Please cancel Claim 11 without prejudice and without dedication or abandonment of the subject matter thereof.

12. A [method] software as claimed in claim [11 wherein,] 10 further including the use of solvents for extraction, said solvents being [the solvents used for extraction is] selected based on the polarity, hydrophilic and hydrophobic nature of the constituents[,] of the sample and its constituents under study.

13. A [method] software as claimed in claim [11 wherein, the] 10 further including the use of an HPLC apparatus, said HPLC apparatus [used] is selected form any commercially available HPLC apparatus with the Photo

Diode Array detector, preferably with a gradient or ternary system of pumps.

14. A [method] software as claimed in claim 10, wherein [11 wherein,] the polarity of the mobile phase [of a non-aqueous and an aqueous solvent of a specific pH] is controlled by varying the ratio of the mobile phase from 0% to 100% of an aqueous [solvents like water or a] buffer of a known pH, along with a non-aqueous solvent [or] like acetonitrile and vice-versa.

15. A [method] software as claimed in claim 10, wherein [11 wherein,] on analysis of 3-D and contour chromatograms using new software called Rainbow, that gives a chromatogram with retention time and wavelength on its [X] X-axis and its Y-axis.

16. A [method] software as claimed in claim 10, wherein [11, wherein,] on analysis of 3-D and contour chromatograms using new software which gives a data having indicated the [vitiation of doshas] "vitiation of doshas" (the balancing of properties) quantitatively in percentage ratio.

17. A [method] software as claimed in claim 10, which uses [11 wherein,] a single solvent ethanol [is used] for extraction of the constituents; same analytical conditions and instrumental parameters [were] are used for all samples to bring the therapeutic generalizations[. The therapeutic

standardization is thus achieved] thereby achieving therapeutic standardization.

Please cancel Claim 18 without prejudice and without dedication or abandonment of the subject matter thereof.

19. A method as claimed in claim 1 which is a computational method of chromatographic finger printing, chemical and therapeutic standardization and bar coding of organic and organo-metallic molecules from a plant, animal or a naturally available or [man made] man-made materials used as medicines, [said] the method comprising

[a)] (a) [selection of medicines and extraction of] selecting plant, animal or a naturally-available or man-made material which possess medicinal value, and extracting the constituents,

[b)] (b) [separation of] separating the constituents into individual [constituents] compounds, generating and converting the 3-D and contour chromatograms into fingerprints,

[c)] (c) analyzing the fingerprints using the software developed, and

[d)] (d) interpreting the data.

20. A method as claimed in claim 1, wherein step iv [19 wherein, it] provides an in-built software for chemical analysis of the constituents present in the

[medicine] extract under study and their conjugative and polarity properties indicating the therapeutic efficacy of the medicine as per the traditional concepts of the medicine using the new software developed.

21. A method as claimed in claim 1, wherein step iv an in-built software [19 wherein, it] provides a novel concept for obtaining [of] chromatographic finger printing of material having medicinal value [herbal medicines which is useful] for the quick identification of the actual profile of the compounds present in the medicine under use along with [their] the therapeutic efficacy of the constituents.

22. A method as claimed in claim 1 wherein in step iv an in-built software [19 wherein, it] provides a novel chromatographic finger printing of herbal medicines and formulations using the contour and 3-D chromatograms of the herbal medicines and formulations is proposed and they are developed on a Photo Diode Array Detector (PDA) of a High Pressure Liquid [Chromatograph. This delineates the data of the spectral properties of the constituents present in the herbal medicines presented in a specific order of polarity under similar experimental analytical conditions] Chromatography, which delineates the data of the spectral properties of the constituents present in the material having medicinal value, presented in a specific order of polarity, generated under similar experimental analytical conditions.

Please cancel Claim 23 without prejudice and without dedication or abandonment of the subject matter thereof.

24. A method as claimed in claim 1, wherein in step vii [19 wherein, said method provides UV-VIS spectra of all the constituents shown in a single image] "The Chromatographic Fingerprint"[, the said fingerprint becomes] is the blue print of the constituents present in an herbal medicine or formulation for an assay and quick identification of the medicine [understudy] under study.

25. A method as claimed in claim 1, wherein [24 wherein,] same standard analytical parameters like extraction with same solvent ethyl alcohol, same run time 0-60min, same mobile phase acetonitrile along with phosphate buffer having a pH in the range of 5.5-7.5, and a same UV-Visible Range of 200-800nm for fingerprinting and chemical and therapeutic standardization.

26. A method as claimed in claim 1, wherein [24 wherein,] the fingerprinting data obtained are [is] used for the study of adulterated, substituted, contradictual and commercial food and drug samples and to identify the pure and impure.

27. A method as claimed in claim 1, wherein fingerprint data obtained are [24

wherein, fingerprinting method is] used for identifying the chemical constituents present in it for the purpose of process standardization, quality control activities and therapeutic standardization of Allopathic, Ayurvedic, Homoeo, Siddha,Unani, Chinese, Tibetan, Kampo (Japanese) medicines.

28. A method as claimed in claim 1, wherein the fingerprinting data obtained are [wherein, fingerprinting method is] used for the study of variation of chemical constituents due to various ecological factors, geological factors, genotypic and phenotypic variations (in plants) in naturally occurring samples and to identify and standardize the chemical constituents in them.

29. A method as claimed in claim 1, wherein the fingerprinting data obtained are [24 wherein, fingerprinting is] used for the study of chemical constituents in synthetically prepared samples and to identify and standardize the chemical constituents in them for chemical and therapeutic standardization [which ever] whichever is applicable.

30. A method as claimed in claim 1, wherein the fingerprinting data obtained are [24 wherein, fingerprinting is] used for the study of chemical constituents in herbal products of single medicine samples and to identify the chemical constituents in them for chemical and therapeutic standardization.

31. A method as claimed in claim 1, wherein the fingerprinting data obtained are [24 wherein, fingerprinting is] used for the study of chemical constituents in herbal products of formulated medicine samples and to identify the chemical constituents in them for chemical and therapeutic standardization.

32. A method as claimed in claim 1, wherein the fingerprinting data obtained are [24 wherein, fingerprinting is] used for the study of variation of chemical constituents in biological samples and to identify and standardize the chemical constituents in them for chemical and therapeutic standardization.

33. A method as claimed in claim 1, wherein the fingerprinting data obtained are [24 wherein, fingerprinting is] used for the study of variation of chemical constituents in different brands of products of single and formulated food and medicine samples and to identify the chemical constituents in them for chemical and therapeutic standardization.

34. A method as claimed in claim 1, wherein in step ix [24 wherein,] preparation of a database of a large number samples gives many generalizations of the therapeutic efficacy of a particular group of plants, classified as a group for a particular disease or therapeutic classification.

35. A method as claimed in claim 1, wherein fingerprint data [24 wherein,

fingerprinting] of medicines facilitates [to categorize and quantify] the categorization and quantification of the constituents of a medicine based on polarity and conjugation from 3-D and contour chromatograms and assess the therapeutic efficacy of the medicine on which humors it is going to act (vitiate).

36. A method as claimed in claim 1, wherein fingerprint data obtained [24 wherein, fingerprinting] enables [to understand and standardize] the understanding and standardization of the Physico-Chemical properties of the medicines like color for the use of therapeutic standardization of medicines and humors (Tri Doshas) using conjugative and polarity properties given in the chromatographic fingerprints.

37. A method as claimed in claim 1, wherein fingerprint data obtained [24 wherein, the fingerprinting method] enables [to understand and standardize] the understanding and standardization of the Physico-Chemical properties of the medicines like Tastes (Rasa) like Sour, Salty, Pungent, Bitter, Astringent (Amla, Lavana, Katu, Tikta, Kashaya as described in Ayurveda) used for therapeutic standardization using conjugative and polarity properties shown in the chromatographic fingerprints.

38. A method as claimed in claim 1, wherein fingerprint data obtained [24 wherein, the fingerprinting method] enables [to understand and standardize]

the understanding and standardization of the Physico-Chemical properties of the medicines like Property, Potency, Metabolite, Specific properties like Chirality of the molecules (Guna, Veerya Vipaka, Prabhava) used for the therapeutic standardization using conjugative and polarity properties of the individual constituents and the whole medicine shown in the chromatographic fingerprints.

39. A method as claimed in claim 1, wherein fingerprint data obtained [24 wherein, the fingerprinting method] enables [to understand and standardize] the understanding and standardization of the Physico-Chemical properties (Gunas) of the medicines like Cold, Hot, Slow in action, Sharp in action, Heavy, Light, Soft Lubricated Supple, Dry (Sheeta, Ushan, Manda, Teekshna, Guru, Laghu, Snigdha, Rooksha as described in Ayurveda) used for the therapeutic standardization using conjugative and polarity properties of the [medicines] medicinal extracts shown in chromatographic fingerprints.

40. A software as claimed in claim 10 is used as a [based] data processor of [3 D] 3-D chromatograms and color contour image of an ingredient, said processing comprising computing means and [capable of]:

[i)] i. an analyzer (extracting colors) for analyzing the colored contour image based on the selection of various colors (with standards mentioned in release notes, life cycle, processing) denoting the concentrations of the

various constituents eluted with time, and polarity based on retention time;

[ii)] ii. an analyzer for analyzing the 3-D chromatograms of the [medicine] medicinal extract using all its 3 dimensional properties of the image;

[iii)] iii. [a] means for generating a chromatogram having peaks at various retention times along with conjugative properties of the molecules eluted with time in a specified order of polarity;

[iv)] iv. an identifier for identifying the compounds in [the said molecules] said extract by the [UV-Vis] Ultra Violet and Visible electromagnetic radiation absorptive properties of the various eluted constituents in the image;

[v)] v. [a] means for correlating the reported biological, therapeutic activity of the of various eluted constituents present in the [medicines understudy] medicinal sample under study based on the polarity and the conjugative properties of the molecules by dividing the fingerprint into therapeutic zones on [X and Y axis] the X-axis and the Y-axis;

[vi)] vi. [a] means for generating a barcode for selected peak(s) using the image coordinates [viz.,] such as X for retention time, Y for wavelength, R for number of red pixels, G for number or green pixels and B for number of blue pixels, provided by the proposed software;

[vii)] vii. [a] means for generating a database of fingerprints and barcodes for the samples, facilitating all kinds of database utilities like Enterprise Resource Planning (ERP) and Customer [Resource] Relationship

Management (CRM) applications; and

[viii)] viii. [a] means for generating a database of the 'display widows' for all the samples to be used by the ENTERPRISE RESOURCE PLANNING (ERP) and CUSTOMER RELATIONSHIP MANAGEMENT (CRM) type of business applications.

41. A processor as claimed in claim 40, further including solvents for extraction, said solvents being [wherein, the solvents used for extraction is] selected based on the polarity, hydrophilic and hydrophobic nature of the constituents, sample and its constituents under study.

42. A processor as claimed in claim 40, further including an HPLC apparatus, said HPLC apparatus being [wherein, the HPLC apparatus used is] selected form any commercially available HPLC apparatus with the Photo Diode Array detector, preferably with a gradient or ternary system of pumps.

43. A processor as claimed in claim 40, wherein [wherein,] the polarity of the mobile phase of a non-aqueous and an aqueous solvent of a specific pH is controlled by varying the ratio of the mobile phase from 0% to 100% of an aqueous [solvents] solvent like water or a buffer of a known pH, along with a non-aqueous solvent or vice-versa.

44. A processor as claimed in claim 40, wherein [wherein,] on analysis of 3-D and contour chromatograms using new software entitled " Rainbow " prepared specifically for this purpose that gives a chromatogram with retention time and wavelength on its [X] X-axis and its Y-axis.

45. A processor as claimed in claim 40, wherein [wherein,] on analysis of 3-D and contour chromatograms using new software which gives [a] data having indicated the vitiation of doshas quantitatively in percentage ratio.

46. A processor as claimed in claim 40, wherein [wherein,] a single solvent ethanol is used for extraction of the constituents; same analytical conditions and instrumental parameters were used for all samples to bring the therapeutic generalizations[. The therapeutic standardization is thus achieved] to achieve the therapeutic standardization.

47. A processor as claimed in claim 40, wherein [wherein,] the software Rainbow has the following features:

[(a) It is software entitled 'Rainbow';

(b)] (a) A software with a [facility] capability of opening chromatographic fingerprint images in different Formats (extensions) like BMP, JPEG, TIF, GIF from the file folders and analyze it for different colors present in the image with single pixel sensitivity;

[(c)] (b) A software with a [facility] capability of display of the pixel information in the form of 1.a graph having a scale of X (0-(min. time scale) and Y (200-800nm) coordinates and 2. a Pie diagram with individual values of each peak (Automatic and Manual) in two separate columns beside the graph;

[(d)] (c) Software with a [facility] capability of printing all the data generated after analysis using the PRINT icon;

[(e)] (d) A software with a [facility] capability of changing the page setup for printing using the PAGE SETUP Icon;

[(f)] (e) A software with a [facility] capability of selecting a part of the image and analyze using the RESIZE Icon;

[(g)] (f) A software with a [facility] capability of opening any number of image analysis windows for different images, and display of status in the WINDOW icon;

[(h)] (g) A software with a [facility] capability of dividing the image [In to] into three Zones at 20 [min interval] minute intervals, using the ZONE Icon;

[(i)] (h) A software with a [facility] capability of inverting the selected image using the INVERT icon;

[(j)] (i) A software with a [facility] capability of switching over to Notepad, Word pad and MS Word, using the EDITOR icon;

[(k)] (j) A software with a [facility] capability of operational information about various features of the Software using, the HELP icon; and

[(l)] (k) Software with a [facility] capability of saving the data generated

using the SAVE AS icon as JPEG file format.

48. Use of fingerprints of contour and 3 –D chromatograms of the constituents as claimed in any of the preceding claims [chemical] are the basis for identification of chemical constituents [to limit the scope of the invention].